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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,906	01/09/2002	Greta Arnaut	58764.000036	1498

21967 7590 11/10/2004

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,906

Applicant(s)

ARNAUT ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-61 and 63-82 is/are pending in the application.
- 4a) Of the above claim(s) 59-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57, 58 and 63-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 57-61 and 63-82 are pending.
2. This application contains claims 59-61 drawn to an invention nonelected with traverse in the response filed 12 November 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The abstract remains not descriptive of the instant invention, which is a nucleic acid encoding Cry2Ae, plants and plant cells transformed with the nucleic acid and a process for using the nucleic acid to render plants resistant to lepidopteran pests. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The objection is repeated for the reasons of record as set forth in the Office action mailed 24 February 2004. Applicant's arguments filed 24 August 2004 have been fully considered but they are not persuasive.

Applicant urges that they have amended the abstract to more clearly describe the instant invention (response pg 11).

This is not found persuasive because the use of the words "variants" suggests amino acid substitutions; "truncation fragments" would more accurately reflect the invention as claimed.

5. The title of the invention is not descriptive of the instant invention, as above. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long. The objection is repeated for the reasons of record as set

forth in the Office action mailed 24 February 2004. Applicant's arguments filed 24 August 2004 have been fully considered but they are not persuasive.

Applicant urges that they have amended the title to more clearly describe the instant invention (response pg 10).

This is not found persuasive because the instant claims are drawn to Cry2Ae proteins, not Bt proteins in general.

6. The rejection of claims 57, 63-74 and 76-77 under 35 U.S.C. 112, first paragraph, for new matter is withdrawn in light of applicant's pointing to support for the phrase.
7. The rejection of claims 58, 62 and 77 under 35 U.S.C. 112, first paragraph, for new matter is withdrawn in light of applicant's pointing to support for the phrase.
8. The rejection of claims 57-58 and 63-78 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of applicant's arguments.
9. The rejection of claims 57-58 and 62-78 under 35 U.S.C. 112, first paragraph, because the specification, for scope of enablement is withdrawn in light of applicant's arguments.
10. The rejection of claims 57-58, 63-70, 74 and 76-77 under 35 U.S.C. 102(e) as being anticipated by Baum et al (US Patent 6,593,293, filed September 1999) taken with the evidence of Datla et al (1997, BioTechnol. Ann. Rev. 3:269-296) is withdrawn.

Claim Objections

11. Claims 71, 73, 75 and 77 are objected to because of the following informalities:

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Claim 71, has an improper article before "leader" in part (b). The objection is repeated for the reasons of record as set forth in the Office action mailed 24 February 2004. Applicant's arguments filed 24 August 2004 have been fully considered but they are not persuasive.

Applicant urges that use of "the" would create a lack off antecedent basis and that the specification uses "a" (response pg 11).

This is not found persuasive. Unless there is more than one leader sequence from the Petunia chlorophyll a/b binding protein gene, "the" is correct, just as "the" is correct before "chlorophyll" in that phrase.

Claim 73 has an improper article before "3'" in line 2. The objection is repeated for the reasons of record as set forth in the Office action mailed 24 February 2004. Applicant's arguments filed 24 August 2004 have been fully considered but they are not persuasive.

Applicant urges that hat use of "the" would create a lack off antecedent basis and that the specification uses "a" (response pg 11).

This is not found persuasive. Unless there is more than one 3' transcript termination and polyadenylation region of the CaMV 35S gene "the" is correct, just as "the" is correct before "35S" in that phrase.

The colons after "from" in claim 75, line 3, and "control" in claim 77, line 3 should be deleted.

12. Claim 70 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The process of parent claim 69 would inherently render a plant resistant to *Chilo suppressalis*, *C. partellus*, *Scirpophaga incertulas*, *S. innotata*, *Cnaphalocrocis*

medinalis, *Marasmia patnalis*, *M. exigua*, and *M. ruralis*. Thus, claim 70 fails to further limit claim 69.

Claim Rejections - 35 USC § 112

13. Claims 64, 66-68 and 71-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 24 February 2004, as applied to claims 62, 64, 66, 68 and 71-78. Applicant's arguments filed 24 August 2004 have been fully considered but they are not persuasive.

It is unclear in claim 64 where the DNA encoding a targeting or transit peptide is located relative to the DNA sequence and the promoter.

Applicant urges that one of ordinary skill in the art would know that a transit peptide is placed upstream of the coding sequence (response pg 17).

This is not found persuasive because the transit peptide coding sequence could be elsewhere on the chimeric gene, for example before a selectable marker. If applicant intends that the transit peptide coding sequence be in operable linkage to the DNA encoding the Cr2Ae protein, the claim should so say.

It is unclear in claim 71 if the components in parts (a)-(c) are present in any order, or in operable linkage.

Applicant urges that one of ordinary skill in the art would know that the elements are operably linked (response pg 18).

This is not found persuasive; if they are operably linked the claim should so say.

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Claim 71, part (a) is indefinite in its recitation of “derived”. It is unclear how the promoters differ from the native promoters.

Applicant urges that one of ordinary skill in the art would know several variants of the 35S promoter have been used (response pg 18).

This is not found persuasive because the specification does not define promoters derived from CaMV 35S.

It is unclear in claim 72 where the DNA encoding the TpssuAt transit peptide is located relative to the promoter, the leader sequence, and the DNA. It is also unclear for what “TpssuAt” is an abbreviation.

Applicant urges that one of ordinary skill in the art would know that a transit peptide is placed upstream of the coding sequence and that the specification states that TpssuAt is a chloroplast transit peptide, citing Krebbers et al (response pg 18).

This is not found persuasive because if they are operably linked the claim should so say. Applicant did not point to any pages of the specification defining TssuAt. Krebbers et al could not be considered because it was not sent.

It is unclear in claim 73 where the transcript termination and polyadenylation region is located relative to the other components of the chimeric gene.

Applicant urges that one of ordinary skill in the art would know that this region is placed downstream of the coding sequence (response pg 18).

This is not found persuasive because if they are operably linked the claim should so say.

It is unclear in claim 75 if the second chimeric gene has a promoter.

Applicant urges that one of ordinary skill in the art would know that the chimeric genes comprise promoters (response pg 19).

This is not found persuasive because if there is a second promoter the claim should so say.

Claim 75, line 4 and claim 78, line 2, are indefinite in their recitation of "derived". It is unclear how the toxic fragments or hybrids derived from a Cry1F protein differ from the Cry1F protein.

Applicant urges that one of ordinary skill in the art would know that a toxic fragment differs from Cry1F by being as toxic fragment rather than the entire protein and that hybrids differ by having part of another cry protein (response pg 19).

This is not found persuasive because the claim is not limited to hybrids involving other Cry proteins or toxic fragments of Cry1F. It is noted that a protein "derived; from another can have no amino acids in common with the original.

It is unclear in claim 77, line 2, which protein, of the many that can be encoded by any DNA, is the one intended.

Applicant urges that the claim has been amended to depend upon only claims 57 and 58, and thus which proteins are covered by the claim are clear (response pg 19).

This is not found persuasive because many proteins can be encoded by any DNA. Applicant also uses the article "a", which suggests more than one is encoded by the DNA. It is noted that replacement of "a" with --the-- would not obviate this rejection.

Claim Rejections - 35 USC § 103

14. Claims 57-58, 63-70, 74, 76-77 and 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Schnepf et al (Microbiol. Mol. Biol. Rev. 62:775-806).

The claims are drawn to a nucleic acid encoding a protein consisting of amino acids 2-49 to 632 of SEQ ID NO:2 or of amino acids 1 to 625-631 of SEQ ID NO:2, or a protein of SEQ ID NO:2, chimeric genes comprising it, plants transformed with it, and a process for using it to render plants insect resistant.

Baum et al teach a nucleic acid, SEQ ID NO:1, which encodes the instant SEQ ID NO:2. Baum et al also teach the expression of the DNA in plants, including corn and cotton, in chimeric gene constructs behind plant promoters, including the CaMV 35S, the FMV 35S, the wound-inducible mannopine synthase, and the SSU promoters, a 5' leader sequence, and with and without chloroplast, vacuolar or secretion transit peptides, and operably linked to a 3' terminator (column 12, lines 30-43; column 23, lines 1-20; column 57, line 50, to column 63, line 22). The plants would inherently be resistant to *Helicoverpa armigera*, *Anticarsia gemmatilis*, *Sesamia nonagrioides*, *S. inferens*, *Chilo suppressalis*, *C. partellus*, *Scirpophaga incertulas*, *S. innotata*, *Cnaphalocrocis medinalis*, *Marasmia patnalis*, *M. exigua*, and *M. ruralis*. Baum et al do not disclose fragments of the nucleic acid encoding a protein consisting of amino acids 2-49 to 632 of SEQ ID NO:2 or of amino acids 1 to 625-631 of SEQ ID NO:2.

Schnepf et al teach that another Cry2 protein is activated by processing at the N-terminal and C-terminal ends, with about 44 amino acids being removed from the N-terminus and several being removed from the C-terminus (pg 783, right column, paragraph 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the nucleic acids taught by Baum et al, to remove about 44 amino acids from the N-terminus and several from the C-terminus of the protein, as described in Schnepf et al. One of ordinary skill in the art would have been motivated to do so because truncation of the modified Cry genes results in more effective expression in plants (Schnepf et al, pg 793, left

column, paragraph 3) and to avoid insect resistance (Schnepf et al, pg 795, left column, paragraph 2),

15. Claim 71 remains rejected and claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Meulewaeter et al (US 6,294,711, filed June 1997). The rejection is repeated for the reasons of record as set forth in the Office action mailed 24 February 2004. Applicant's arguments filed 24 August 2004 have been fully considered but they are not persuasive.

Applicant urges that no objective reason has been provided to combine the cited references (response pg 23).

This is not found persuasive because selection of a particular untranslated leader sequence is an obvious design choice. Unless unexpected results are shown, selection of one leader sequence over another does not make the claimed invention non-obvious.

16. Claim 72 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al in view of Meulewaeter et al as applied to claim 71 above, and further in view of Corbin et al (US 6,489,542, filed November 1998). The rejection is repeated for the reasons of record as set forth in the Office action mailed 24 February 2004X. Applicant's arguments filed 24 August 2004 have been fully considered but they are not persuasive.

Applicant urges that no objective reason has been provided to combine the cited references (response pg 23).

This is not found persuasive because selection of a particular transit peptide sequence is an obvious design choice. Unless unexpected results are shown, selection of one transit peptide over another does not make the claimed invention non-obvious.

17. Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al in view of Meulewaeter et al as applied to claim 71 above, and further in view of Mettler et al (US Patent 6,114,608, filed March 1998). The rejection is repeated for the reasons of record as set forth in the Office action mailed 24 February 2004. Applicant's arguments filed 24 August 2004 have been fully considered but they are not persuasive.

Applicant urges that no objective reason has been provided to combine the cited references (response pg 23).

This is not found persuasive because selection of a particular termination and polyadenylation region is an obvious design choice. Unless unexpected results are shown, selection of one termination and polyadenylation region over another does not make the claimed invention non-obvious.

18. Claims 75 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Malvar et al (US 6,156,573, filed November 1996). The rejection is repeated for the reasons of record as set forth in the Office action mailed 24 February 2004. Applicant's arguments filed 24 August 2004 have been fully considered but they are not persuasive.

Applicant urges that no objective reason has been provided to combine the cited references (response pg 23).

This is not found persuasive because selection of a particular second chimeric gene is an obvious design choice. Unless unexpected results are shown, selection of one second chimeric gene over another does not make the claimed invention non-obvious.

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Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

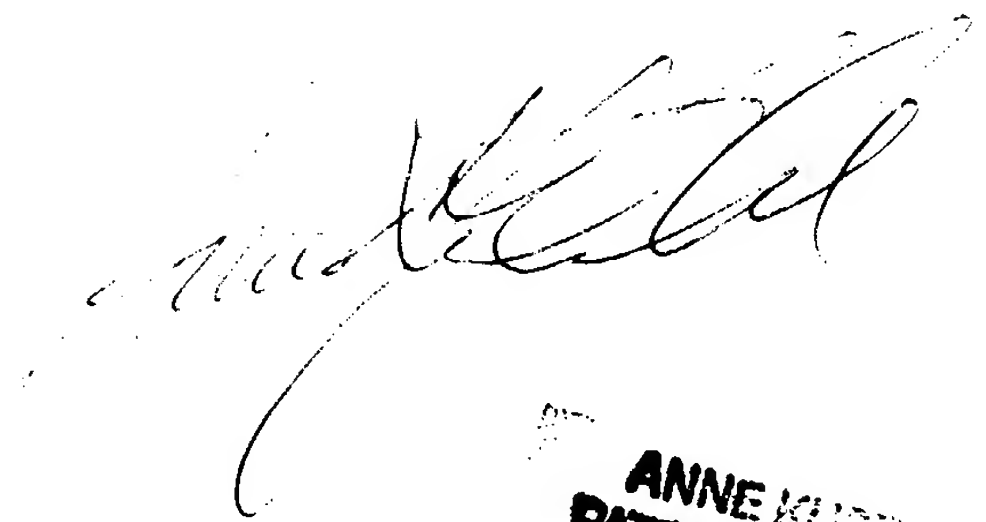
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
November 8, 2004


**ANNE KUBELIK
PATENT EXAMINER**